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Customer No. 23932 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:) Atty. Docket No.: 47168-00033USC
Keith D. Beaty) Examiner: Paul Prebilic
Application No.: 09/259,432) Group Art Unit: 3738
Filed: March 1, 1999)
For: Implant Surface Preparation)

DECLARATION OF PRABHU GUBBI

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

- I, Prabhu Gubbi, declare that:
- A. I reside at 4445 SW Oakhaven Lane, Palm City, FL 34990.
- B. I have degrees in Mechanical Engineering and Foundry Engineering from Bangalore University, India. I also have a Ph.D. degree in Materials Engineering from Auburn University. Since receiving my Ph.D., I have been employed as an engineer with several corporations where I have worked as a material scientist. Currently, I am a materials scientist with Implant Innovations, Inc ("3i").
- C. In the course of my work at 3i, I have examined numerous surfaces of objects used in dental implantology. One of the machines that I use to examine these surfaces is a Scanning Electron Microscope (SEM). The machine that I use is made by Aspex Instruments LLC and its Model number is PSEM II. This machine is about 4 years old.

- D. Within the past several months, I have reviewed several dental implant surfaces from other manufacturers. I understood that the purpose of my review was to develop a summary of competitive implant surfaces that were to be submitted to the U.S. Patent & Trademark Office in connection with the present patent application, which is assigned to 3i.
- E. When developing each implant sheet, I developed a picture of the package in which the implant came (assuming it had a package), an SEM picture at 25X of the implant, and an SEM picture at 2000X to see the microstructure on the implant surface.
- F. I have tried to determine the manufacturing date of each implant as accurately as possible based on the information provided by implant manufacturers on the package. Most of the manufacturers have placed either a "sterilization" date or a "use before" date (i.e., "expiration" date) on the package. For those manufacturers that provide only a "use before" or "expiration" date, it was assumed that the implant was manufactured at least two years earlier. Some manufactures provide a "lot number" which suggests a manufacturing date in its code. Further, because it is my understanding that implant manufacturers have provided sterile implants to clinicians since at least 1990, any non-sterile implants were assumed to be from the 1980's.
- G. Implants in 35 through 61 are from lawsuit civil action #91-C-4632, filed in the Northern District of Illinois related to US Patent #4,330,891, which was concluded in 1998. These implants are believed to have been made in the 1970s, 1980s or early 1990s. The extent, if any, of the sales or other public disclosure of these implants is currently not known.
 - H. The enclosed report contains one sheet on each of the following 61 implants.
 - . 1. Institut-Straumann AG titanium plasma sprayed hollow cylindrical implant in an unsterilized package believed to be from the 1980's

- 2. Institut-Straumann AG titanium plasma sprayed hollow cylindrical implant in an unsterilized package believed to be from the late 1980's
- 3. Calcitek HA-coated "Integral Omniloc" implant believed to be from 1995
- 4. Calcitek HA-coated "Integral Omniloc" implant believed to be from 1990
- 5. Imtec HA-coated implant distributed by Osteomed Inc. believed to be from 1994
- 6 Interpore HA-coated implant believed to be from 1989
- 7. Interpore titanium plasma sprayed implant believed to be from 1993
- 8. Minimatic titanium plasma sprayed implant believed to be from 1993
- 9. Stryker HA-coated implant believed to be from 1987
- 10. The "O" Company push-in implant with blasted surface believed to be from 1994
- 11. Impla-Med HA-coated implant believed to be before 1992
- 12. Collagen Biomedical HA-coated implant believed to be from 1991
- 13. Steri-Oss HA-coated implant believed to be from 1990
- 14. Friedrichsfeld titanium plasma sprayed implant believed to be distributed in Germany in 1991
- 15. Lifecore Biomedical titanium plasma sprayed implant believed to be from 1995
- 16. Stryker titanium plasma sprayed implant believed to be from 1992
- 17. Mathys threaded implant believed to be from 1992
- 18. Nobelpharma machined implant believed to be from 1991
- 19. Nobelpharma machined implant believed to be from 1987

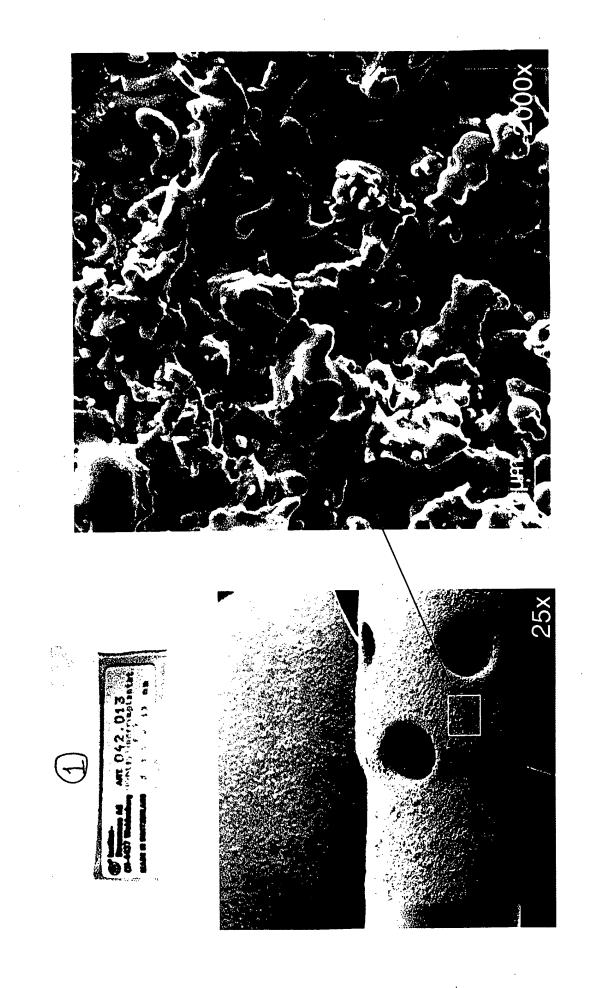
- 20. Miter, Inc. blade-style implant with blasted surface believed to be from 1986
- 21. Miter, Inc. blade-style implant with blasted + etched surface believed to be from 1987
- 22. Astra Dental machined implant believed to be before 1996
- 23. Calcitek HA-coated "Integral SD" implant believed to be from 1988
- 24. Lifecore Biomedical HA-coated implant believed to be from 1995
- 25. Lifecore Biomedical machined implant believed to be from 1995
- 26. Collagen Biomedical machined implant believed to be from 1990
- 27. Institut Straumann titanium plasma sprayed hollow screw implant in an unsterilized package believed to be from the 1980's
- 28. Institut Straumann titanium plasma sprayed screw implant in an unsterilized package believed to be from the 1980's
- 29. Astra Tech screw implant with blasted surface believed to be before 1997
- 30. Core-Vent screw implant with blasted surface believed to be from 1996
- 31. Straumann titanium plasma sprayed implant believed to be before 1996
- 32. Institut Straumann titanium plasma sprayed implant believed to be before 1995
- 33. Dentsply Core-Vent HA-coated implant believed to be before 1996
- 34. Dentsply Core-Vent machined implant believed to be before 1996
- 35. Cherchev Implant implant appears to have blasted surface
- 36. Samson Titanium Screw implant appears to have machined surface
- 37. Oratronics Spiral implant appears to have a slightly roughened surface
- 38. Oratronics Blade implant appears to have a slightly roughened surface
- 39. Synthodont implant appears to have a blasted surface

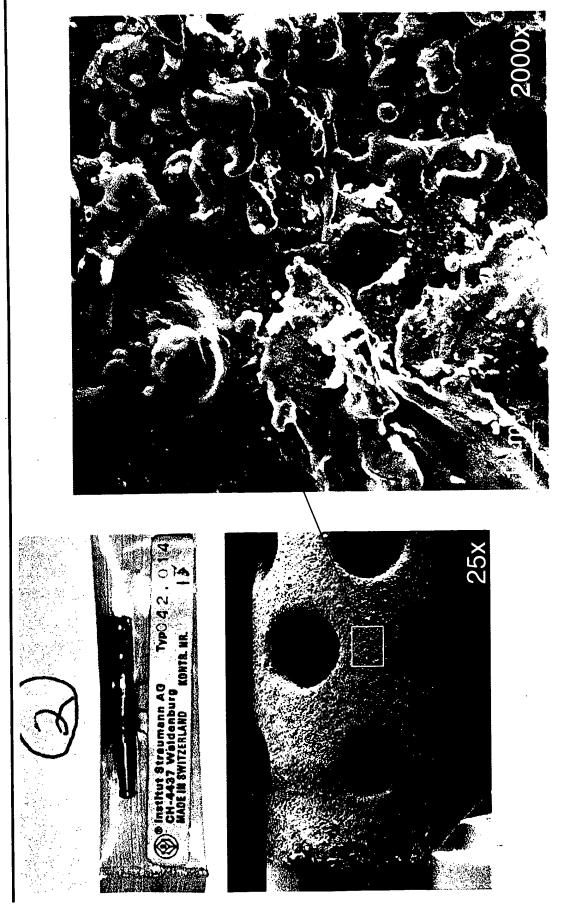
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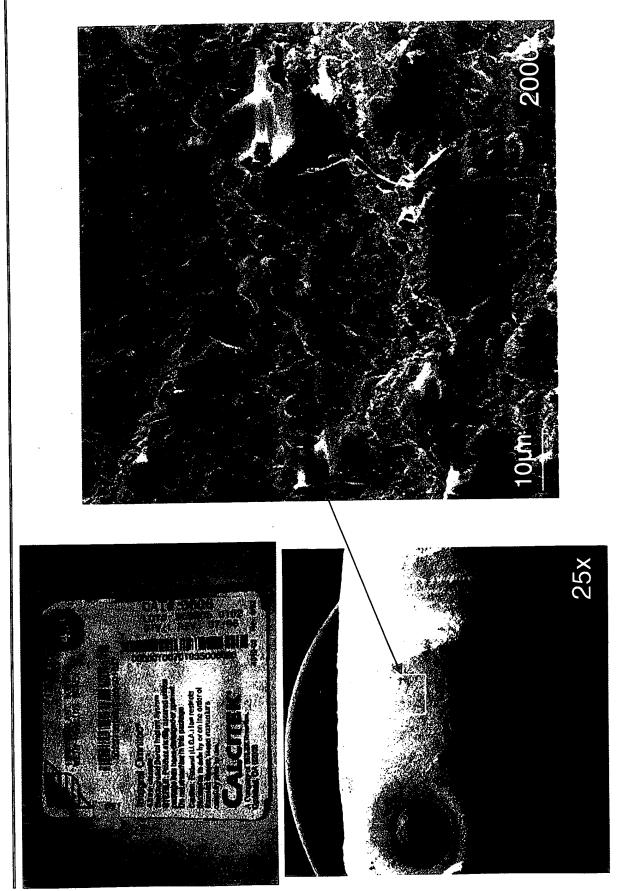
- 40. Vitradent implant appears to have a slightly roughened surface
- 41. Zimmer Mandibular Staple implant appears to have blasted surface
- 42. MI-150-TI implant appears to have machined surface
- 43. Ti 1968-70 implant appears to have a slightly roughened surface
- 44. Cast Vitallium Surgical implant appears to have a blasted surface
- 45. Park Dental implant appears to have a slightly roughened surface
- 46. Babbush Implants implant appears to have blasted surface
- 47. Oratronics implant appears to have a slightly roughened surface
- 48. Swingos implant appears to have a slightly roughened surface
- 49. Konkoly implant appears to have a slightly roughened surface
- 50. Sulzer Protusil implant appears to have a titanium plasma sprayed surface
- 51. IRC Curved implant appears to have a slightly roughened surface
- 52. Oratronics implant appears to have a slightly roughened surface
- 53. Hamilton implant appears to have a slightly roughened surface
- 54. Barton Partial implant appears to have blasted surface
- 55. Arenson implant appears to have blasted surface
- 56. IRC Clinical Retrieval implant appears to have a slightly roughened surface
- 57. Park Dental implant appears to have blasted surface
- 58. Oratronics implant appears to have a slightly roughened surface
- 59. Interplant implant appears to have blasted surface
- 60. Subperiosteal implant appears to have a slightly roughened surface

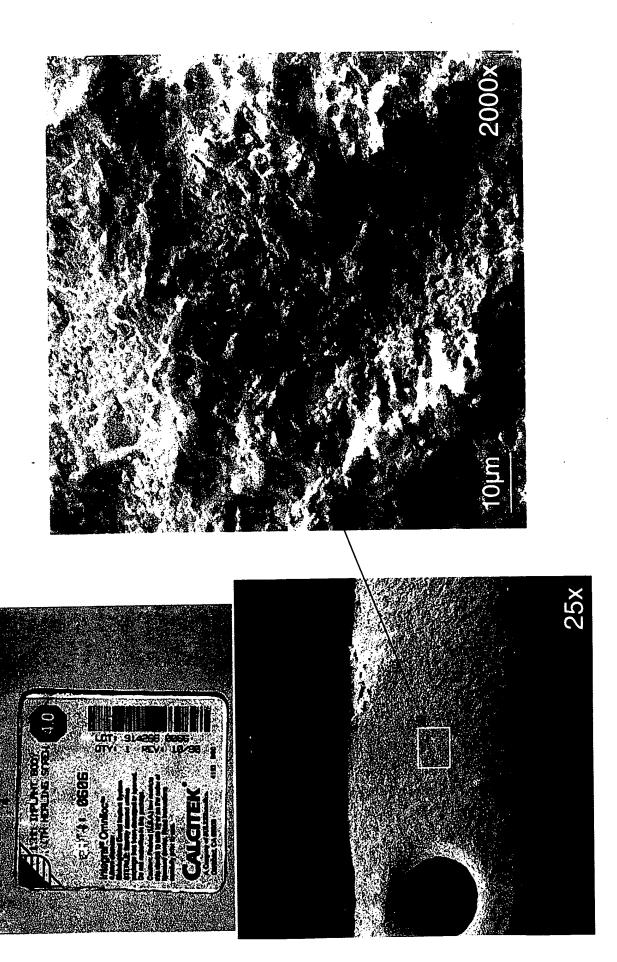
61. Continuous Blade – implant appears to have a machined surface

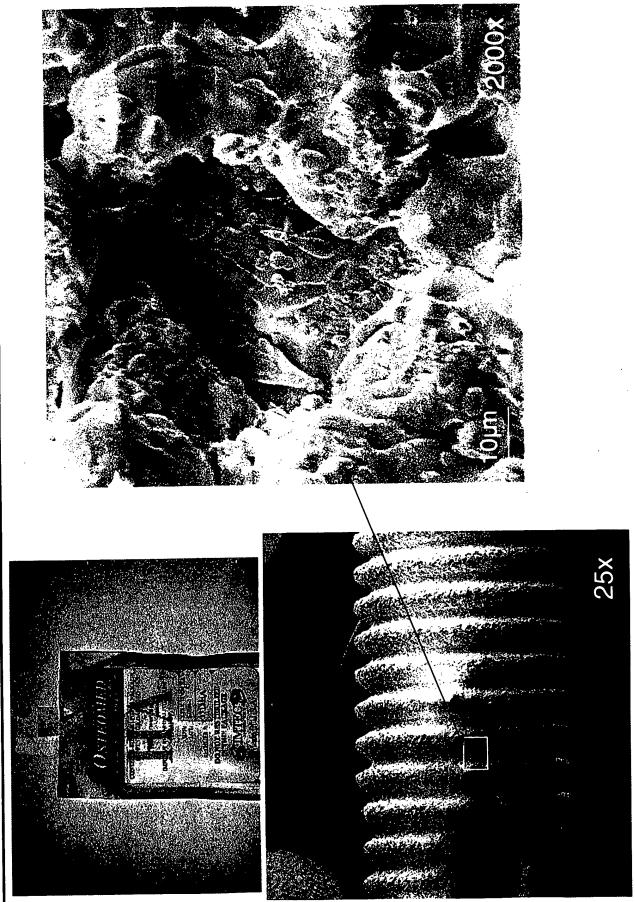
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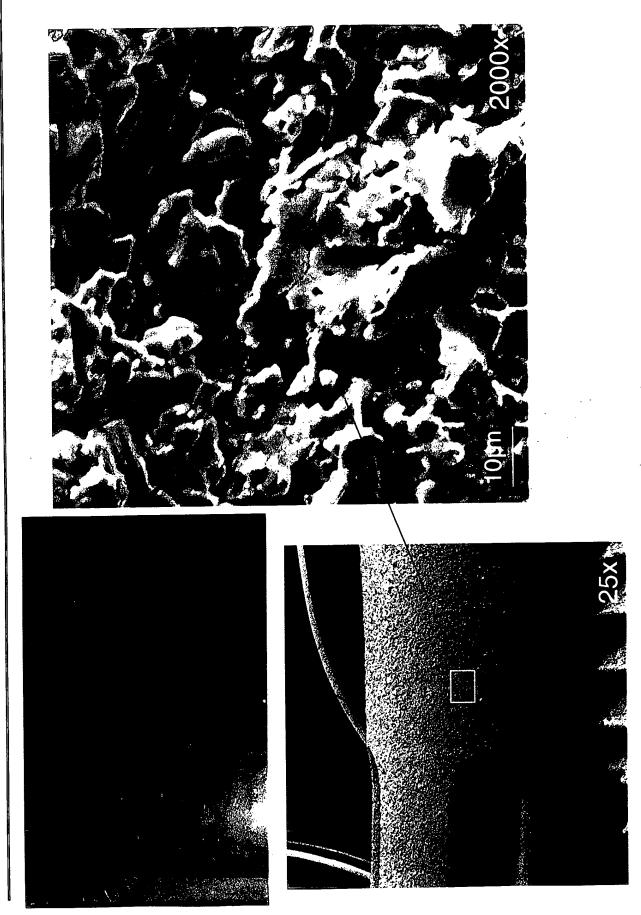


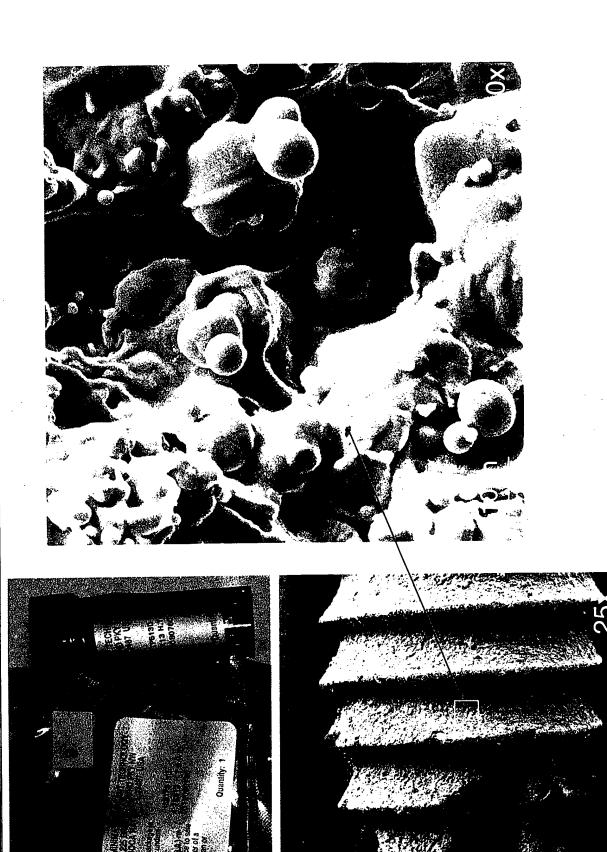


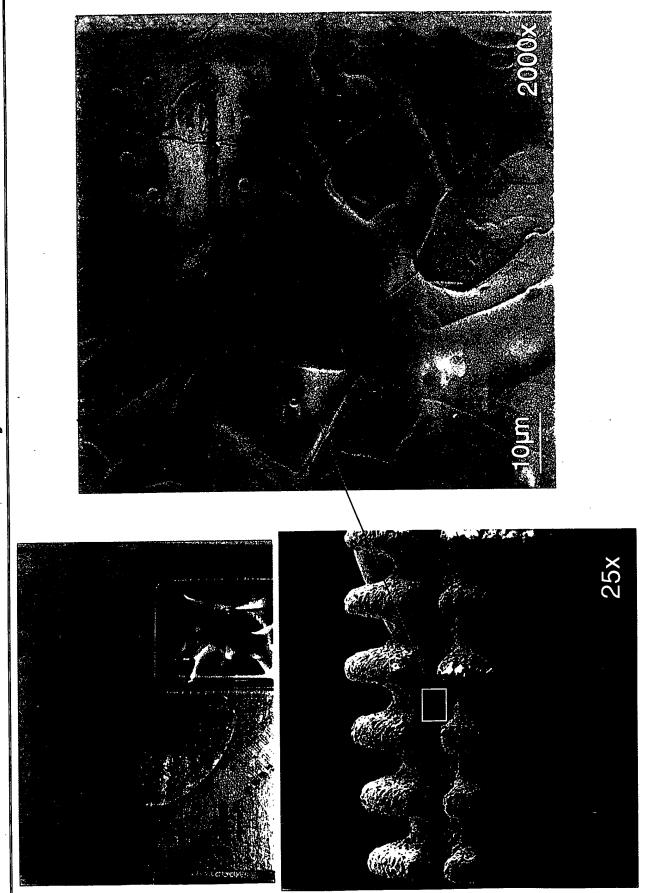


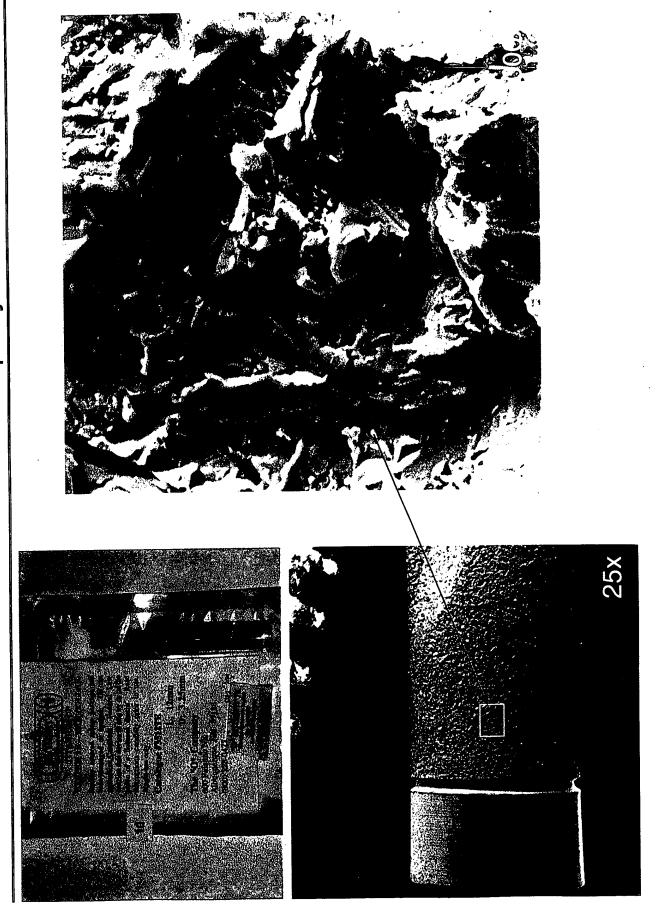


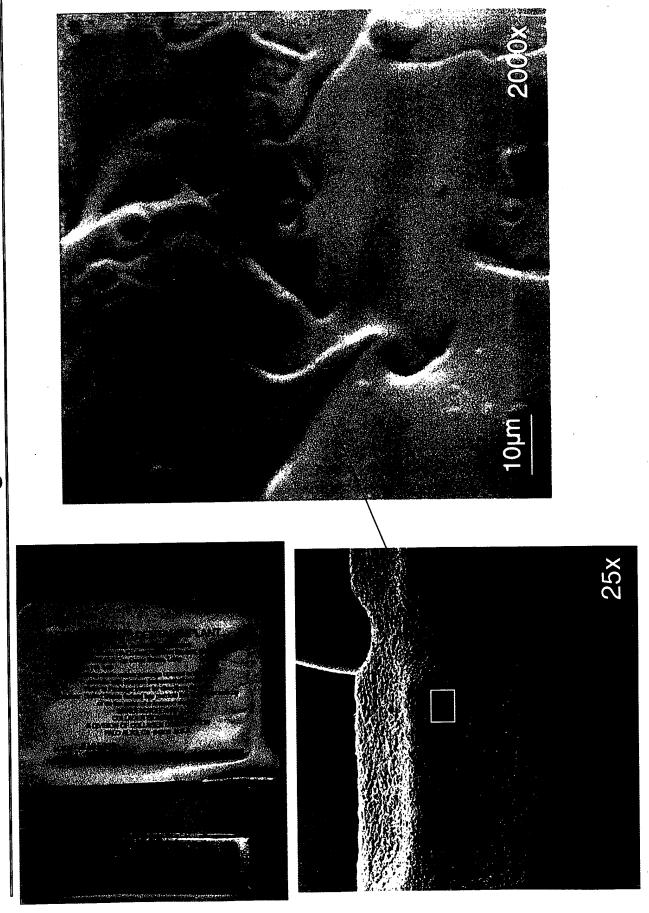
6. Interpore

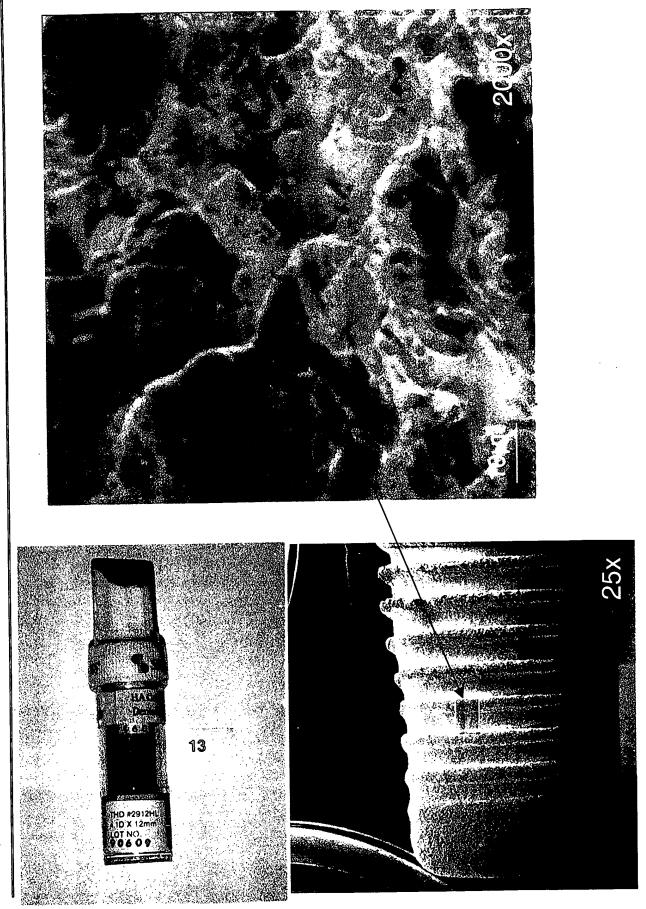


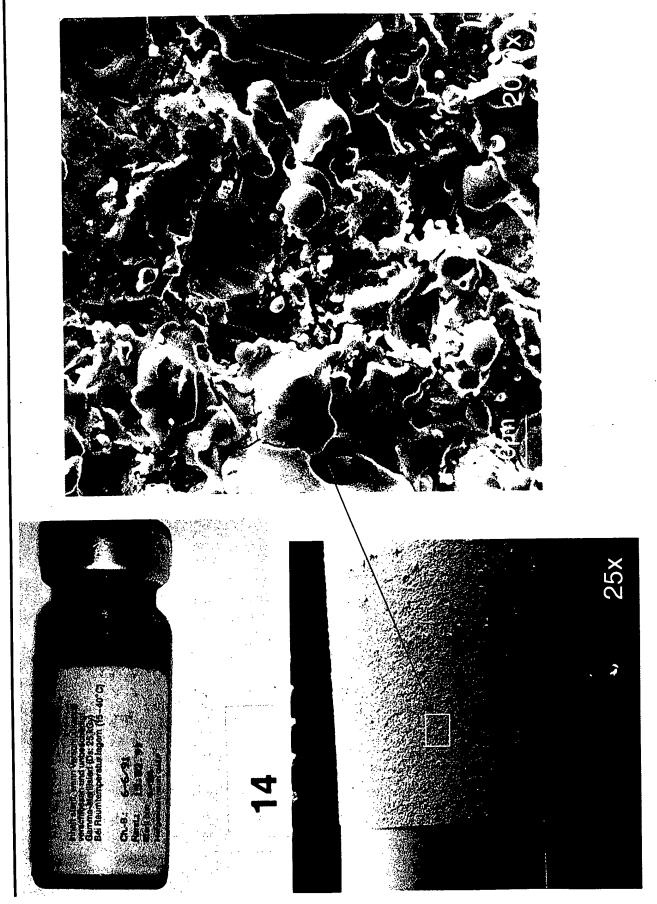


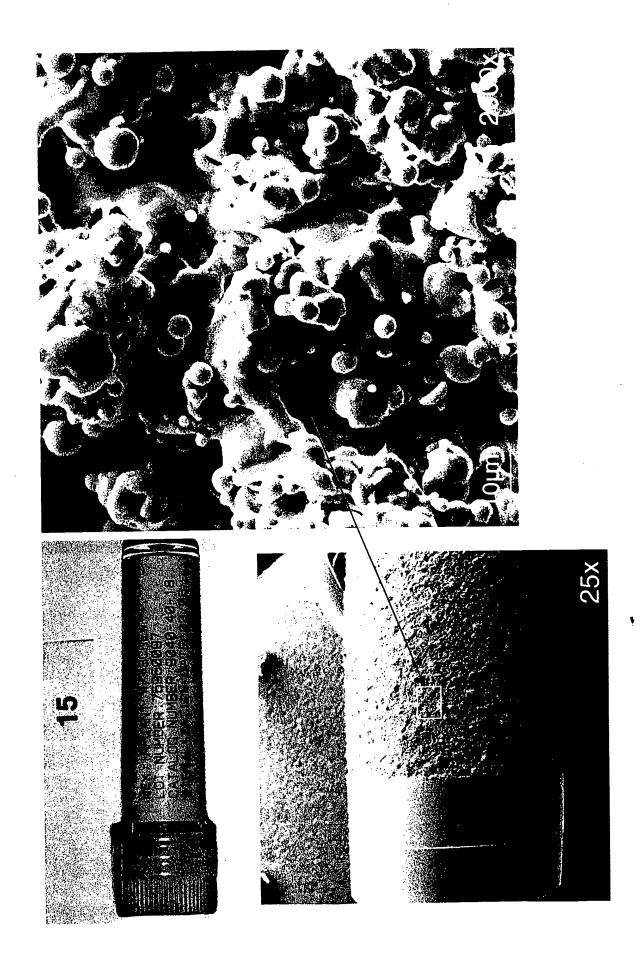


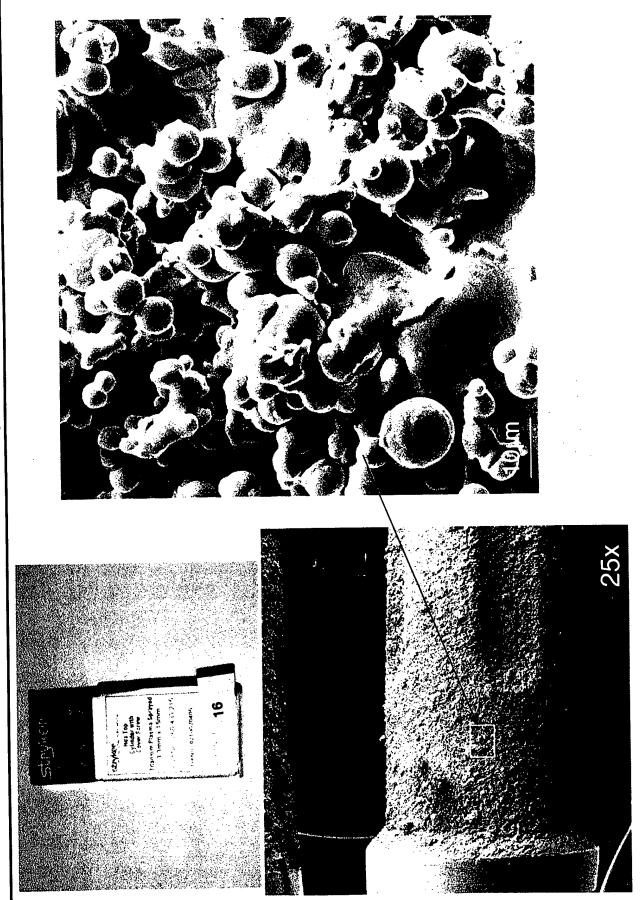


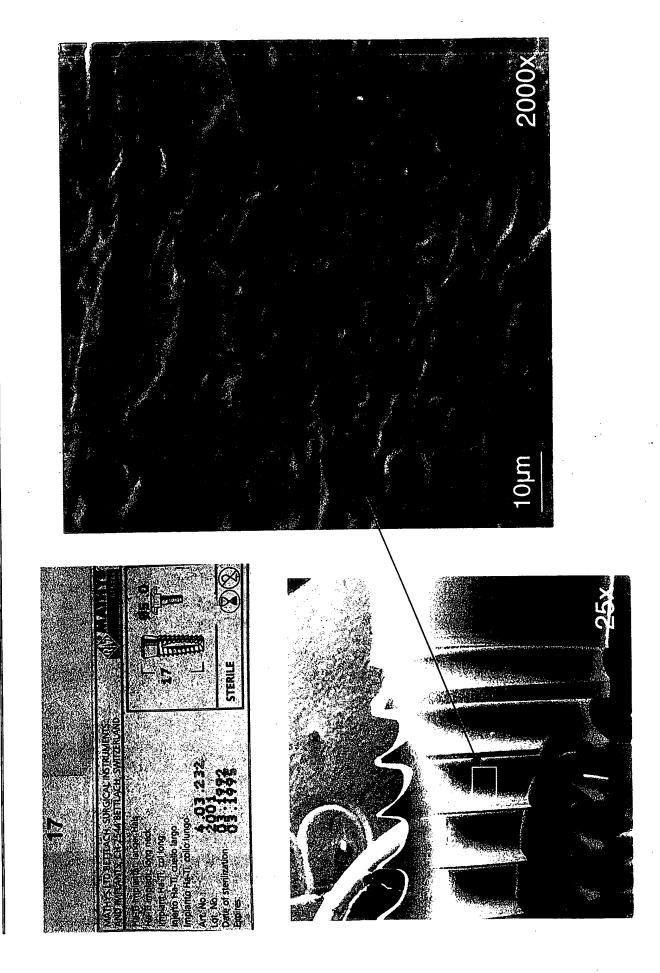


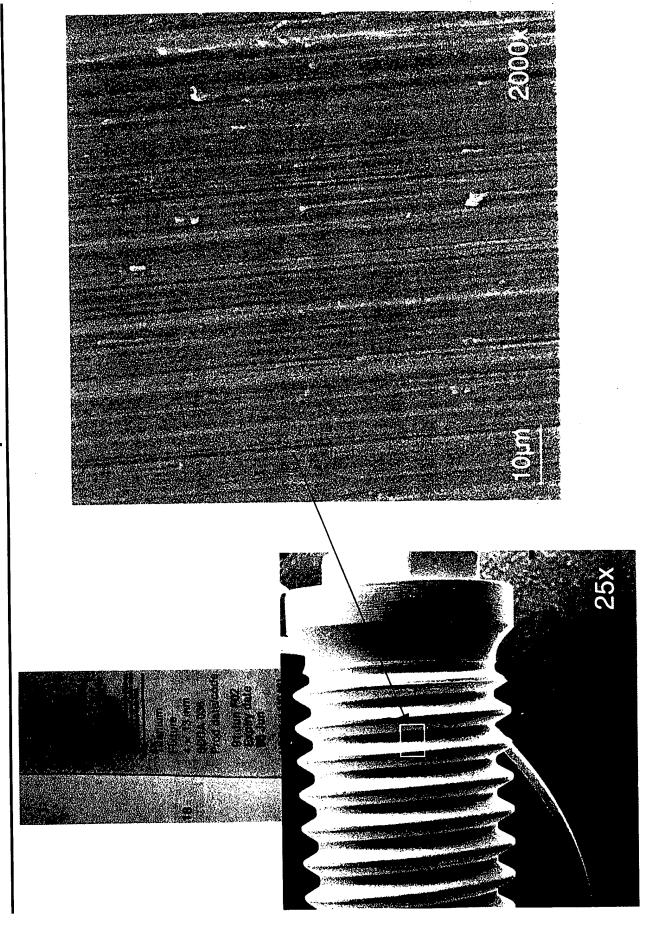


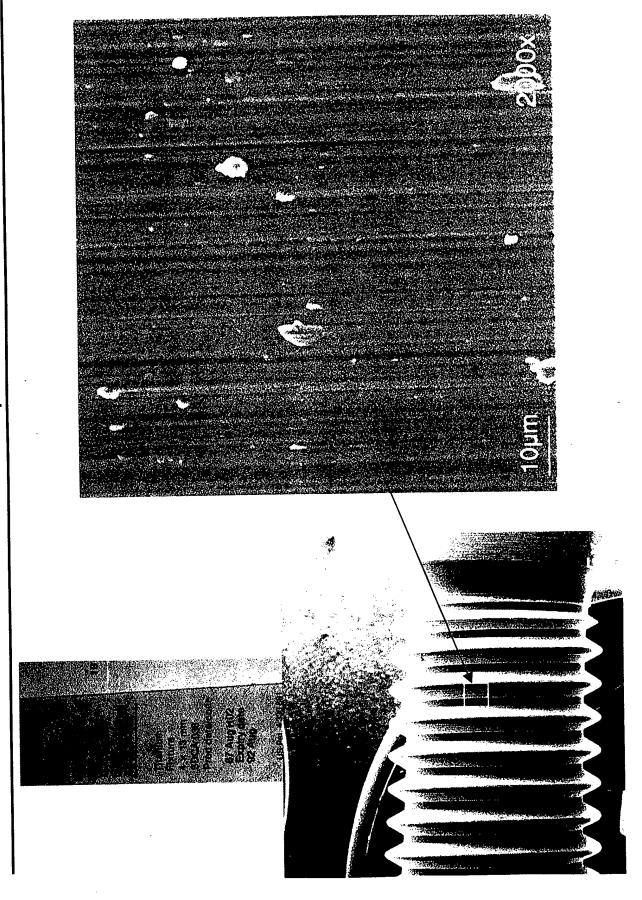


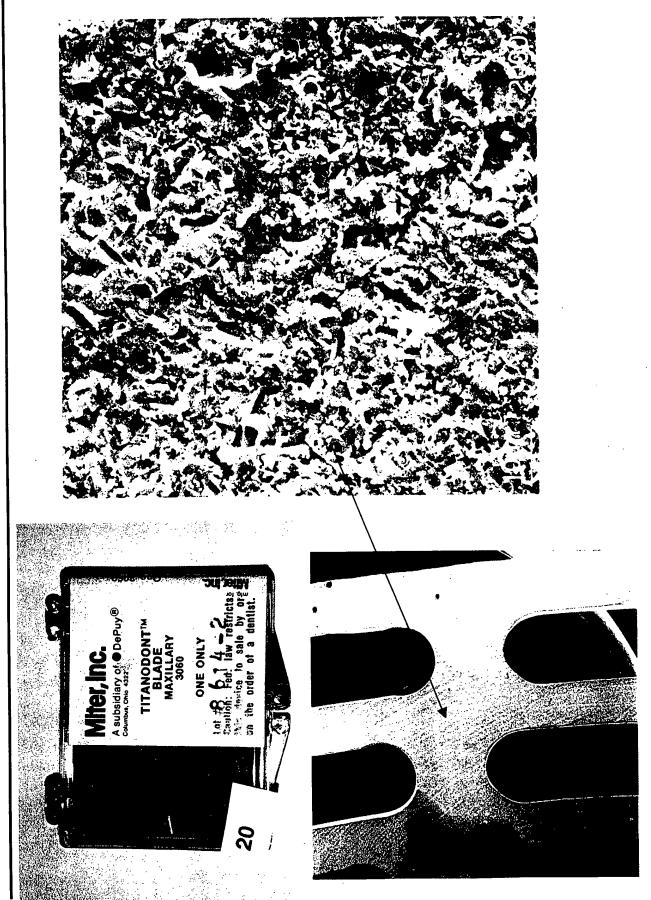


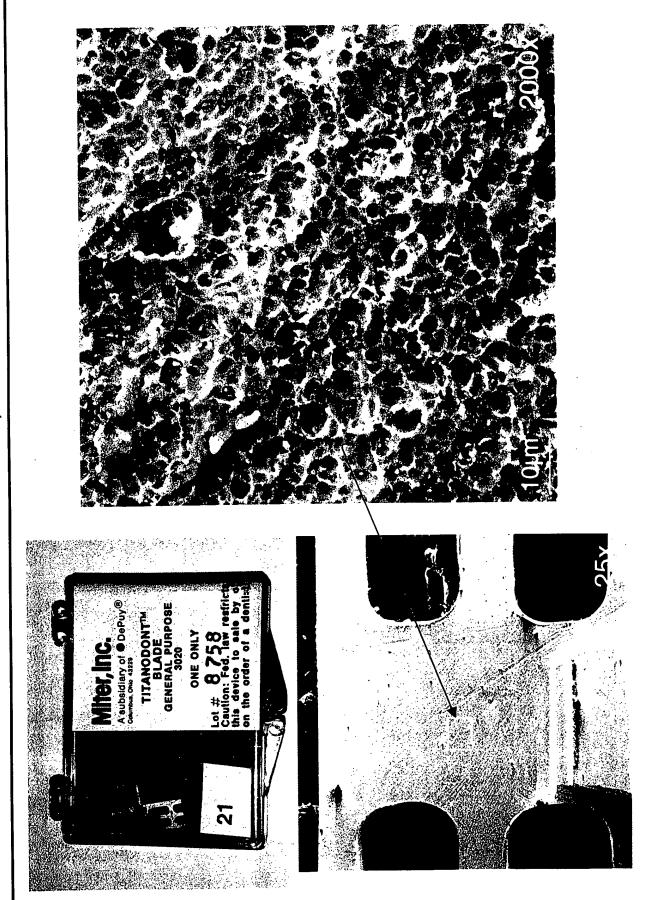


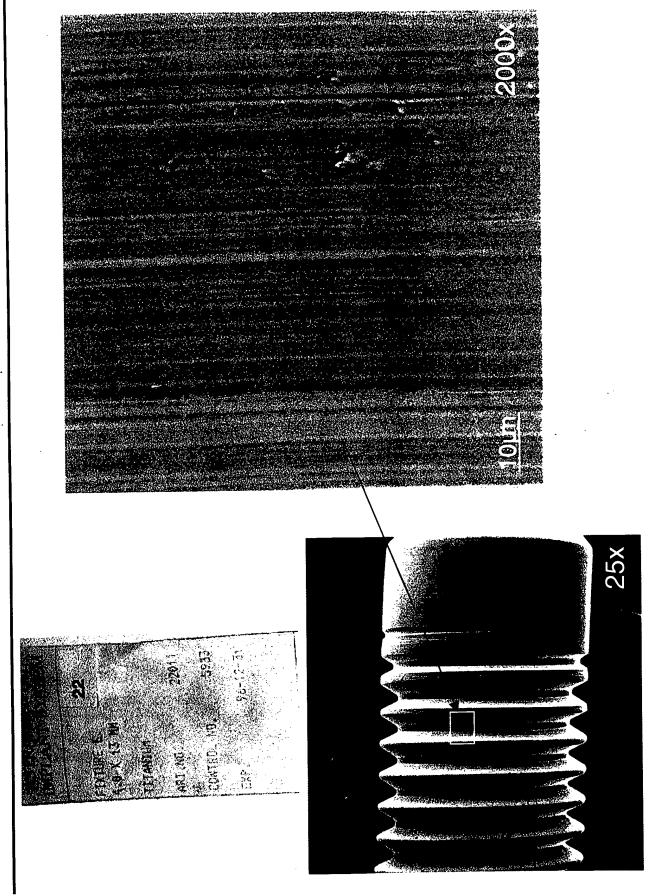




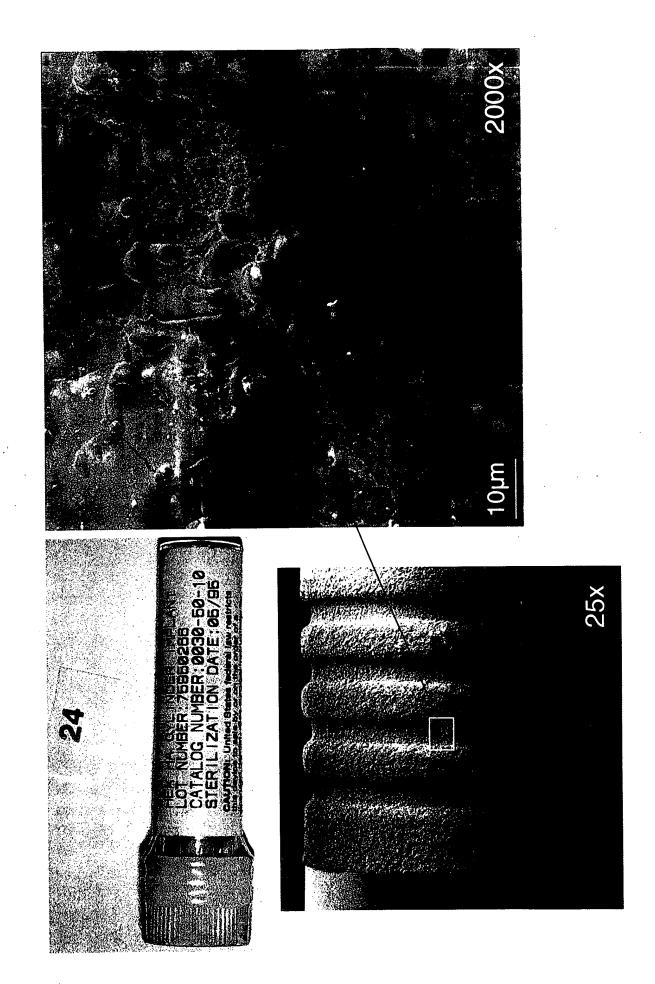


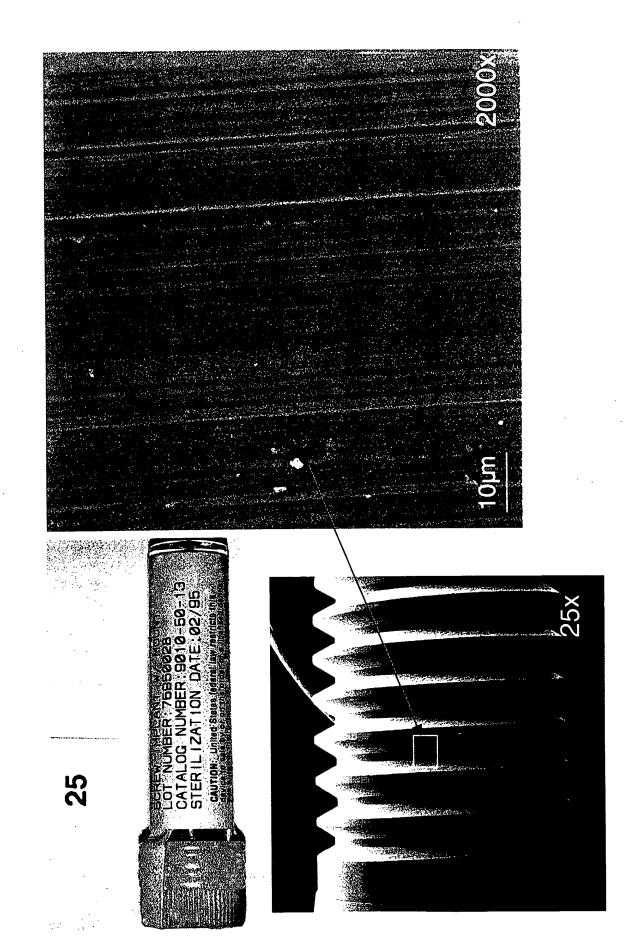


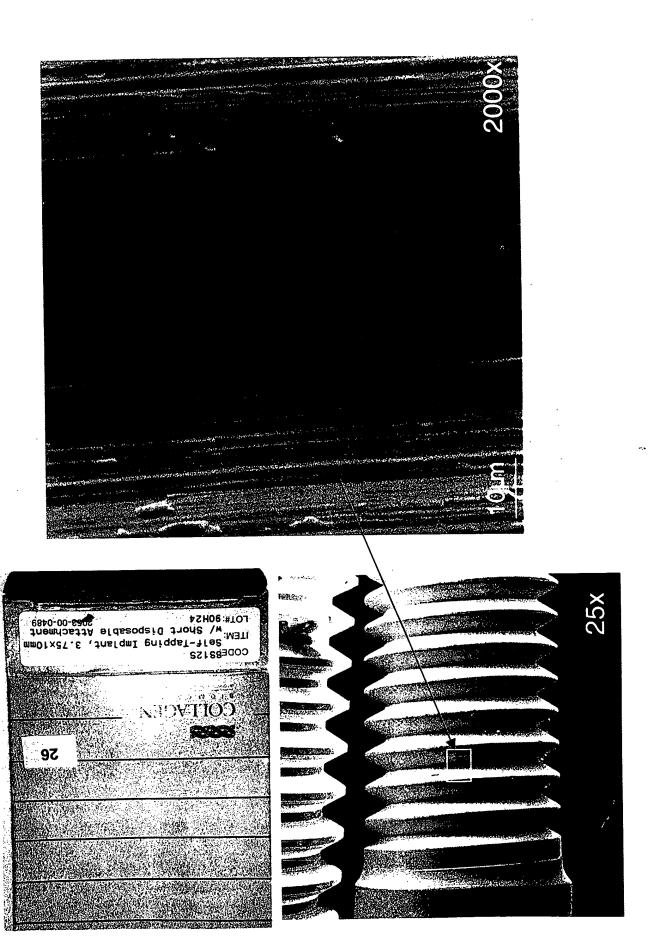


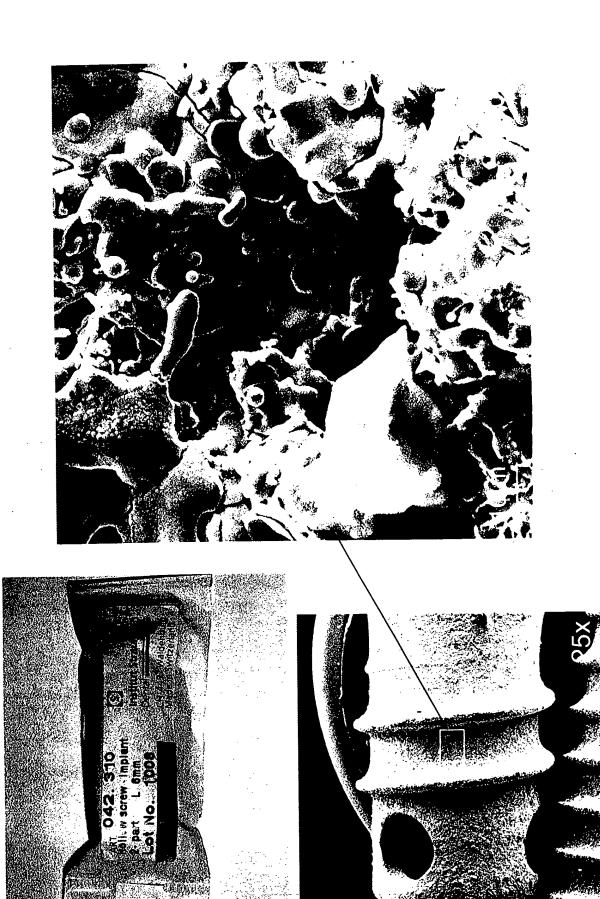


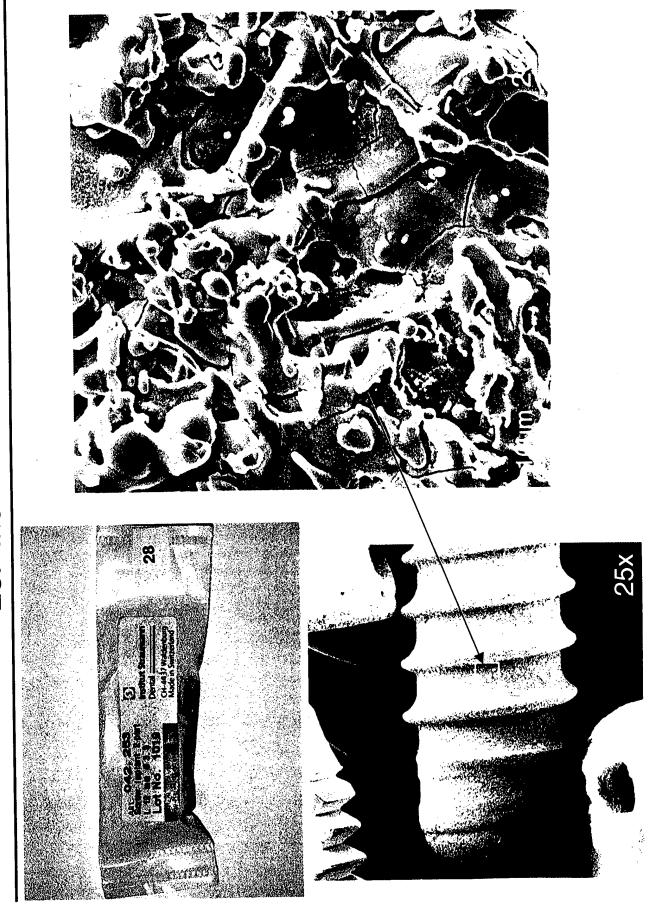
23. Calcitek

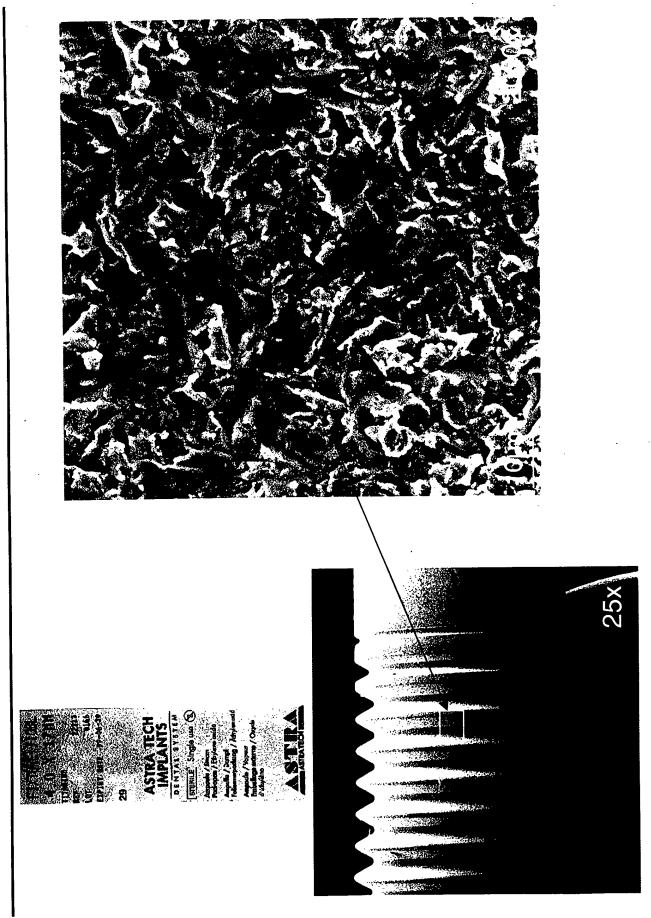




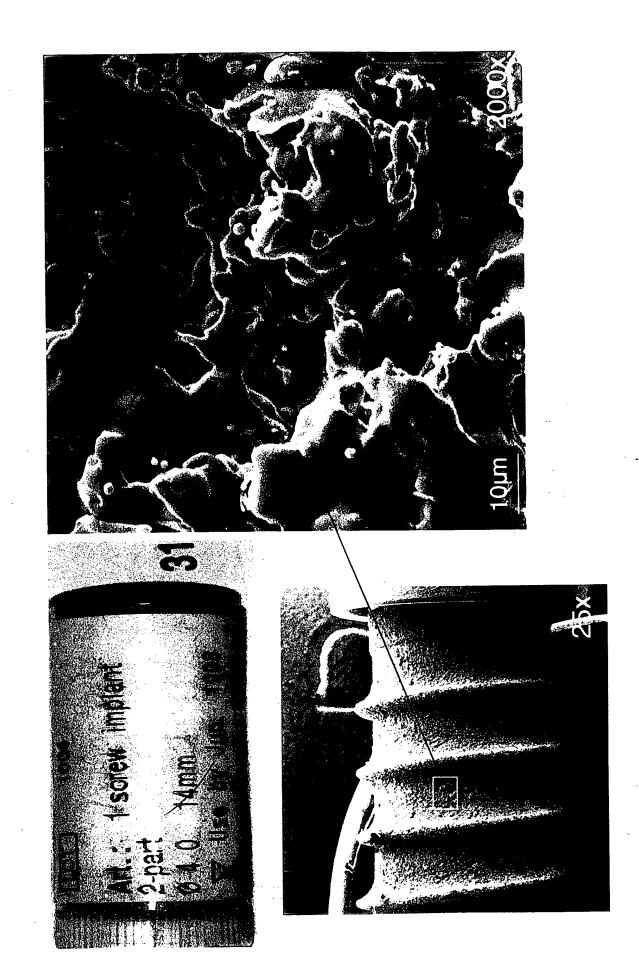


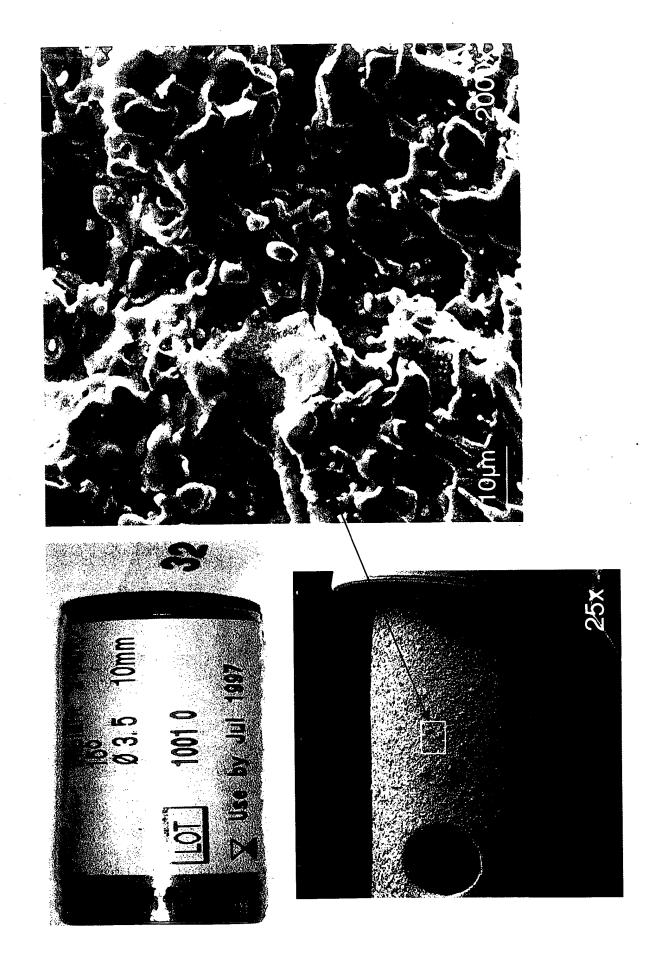


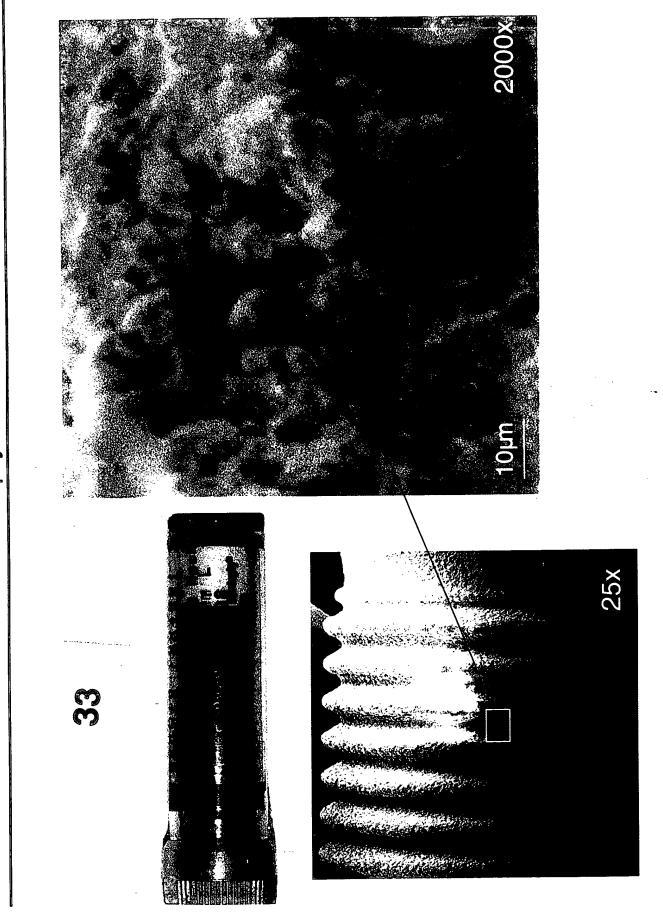


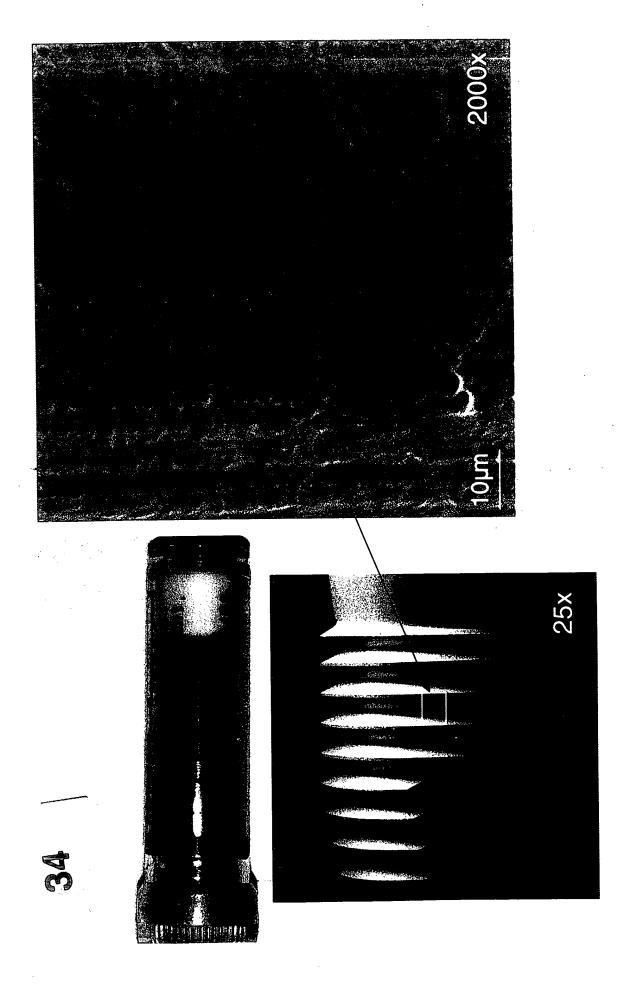


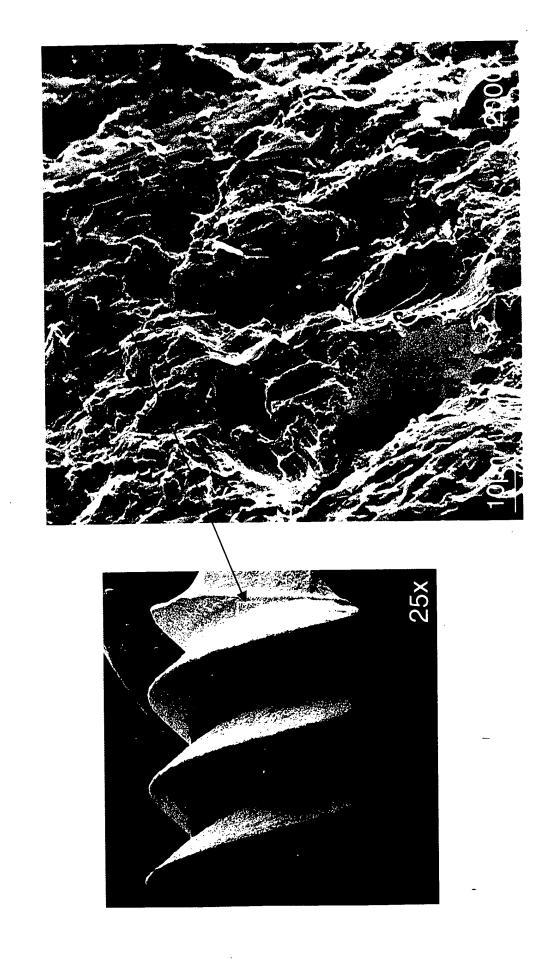


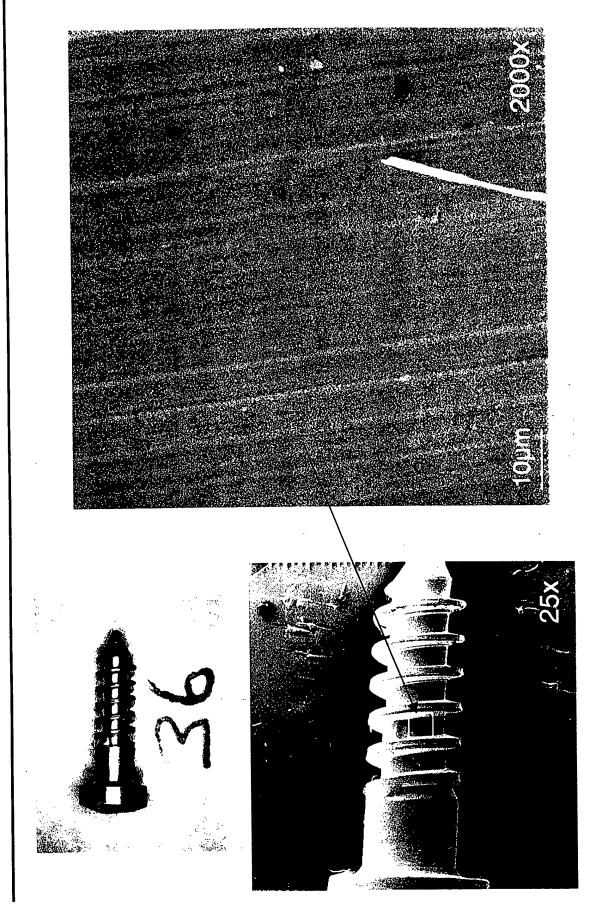


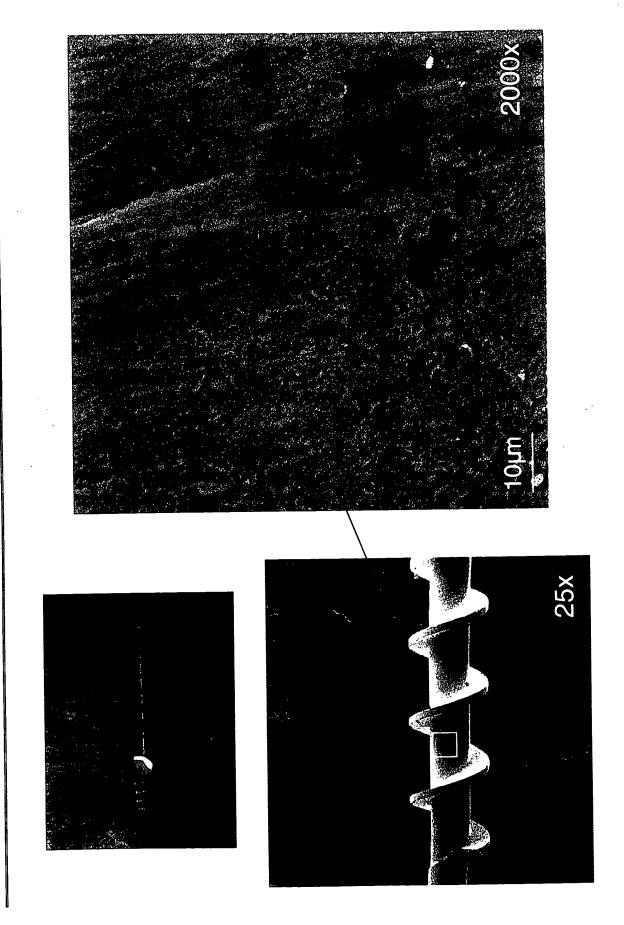


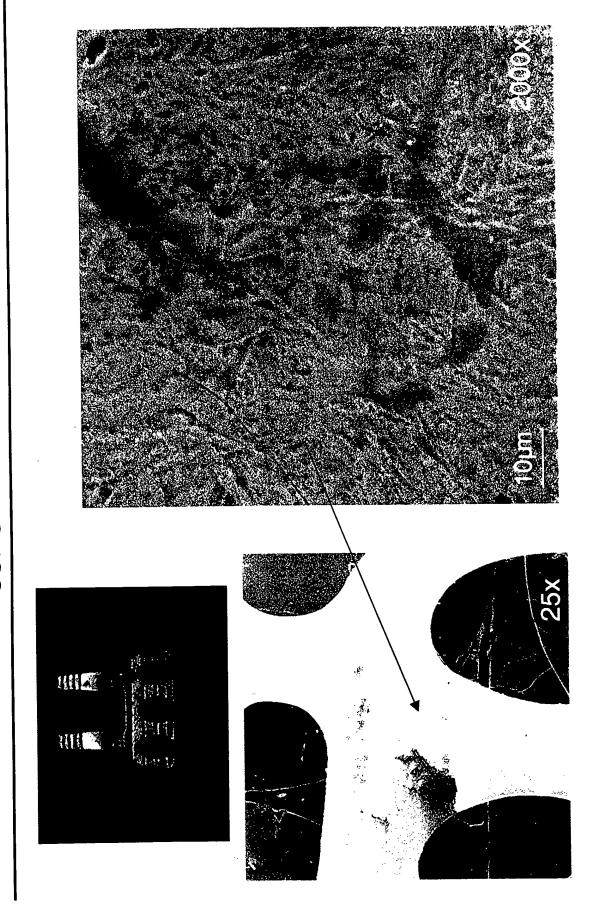


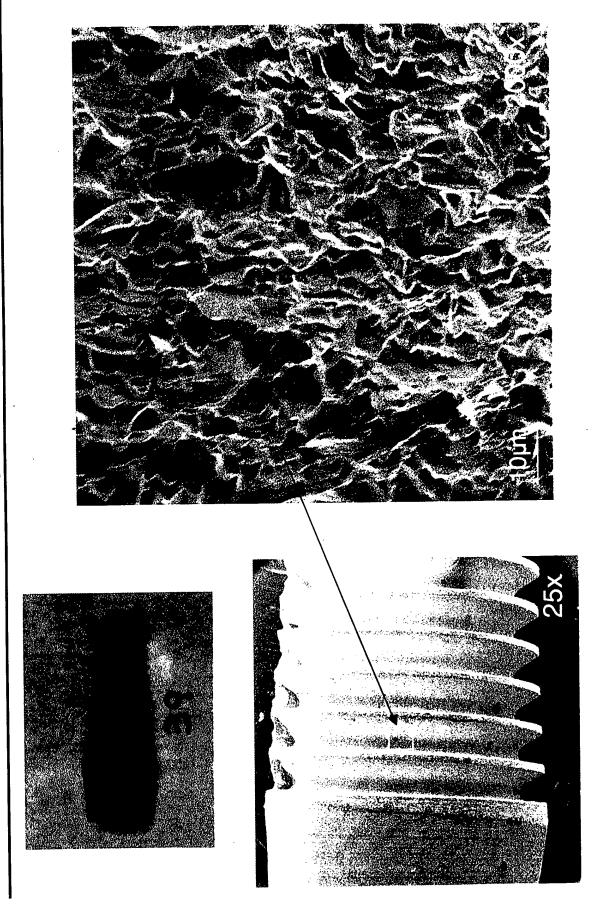


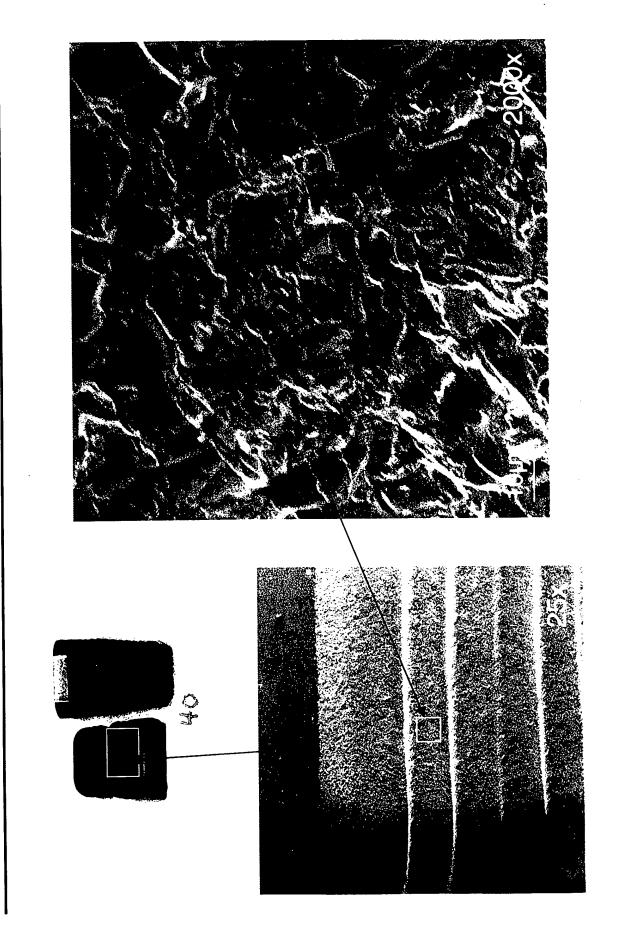


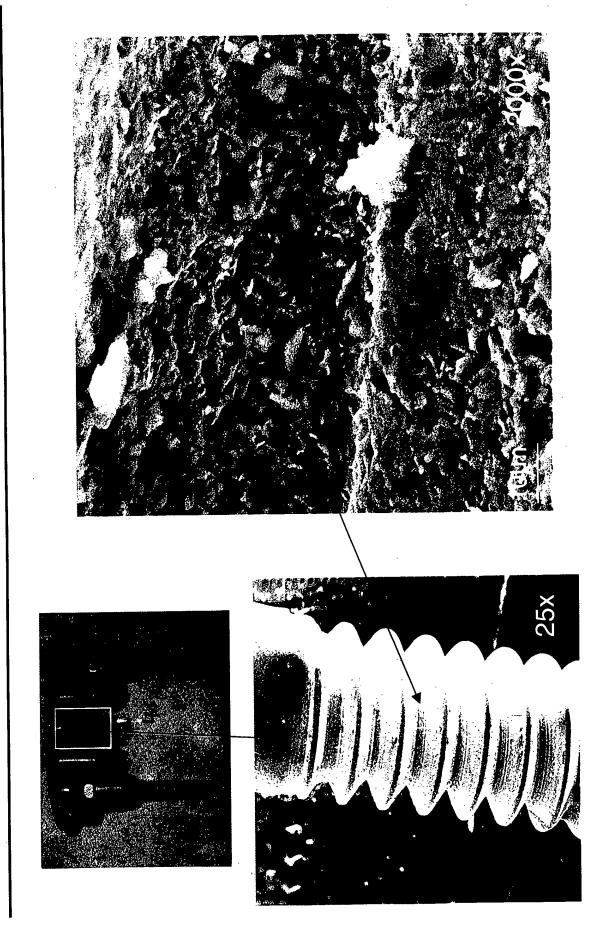


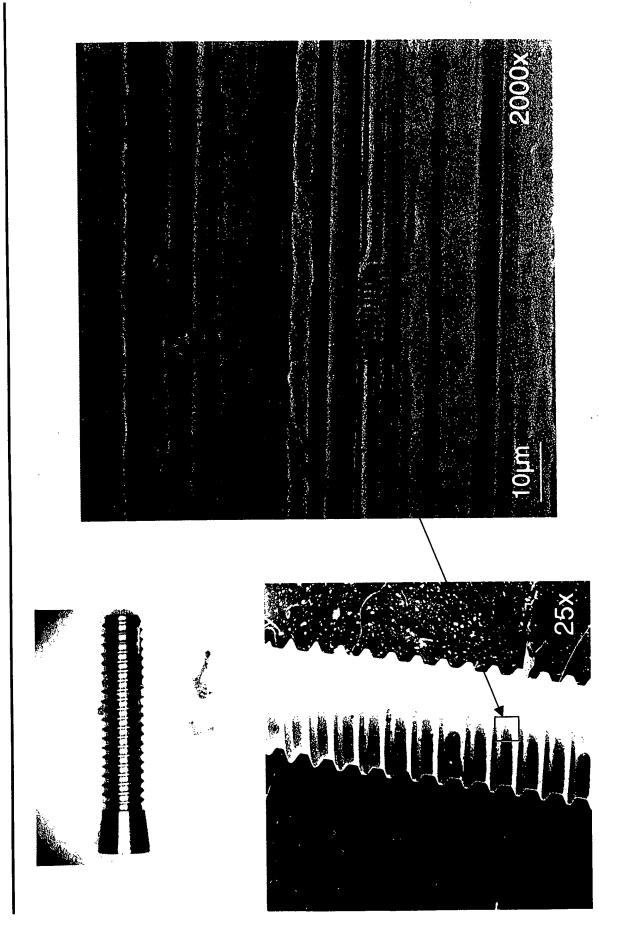


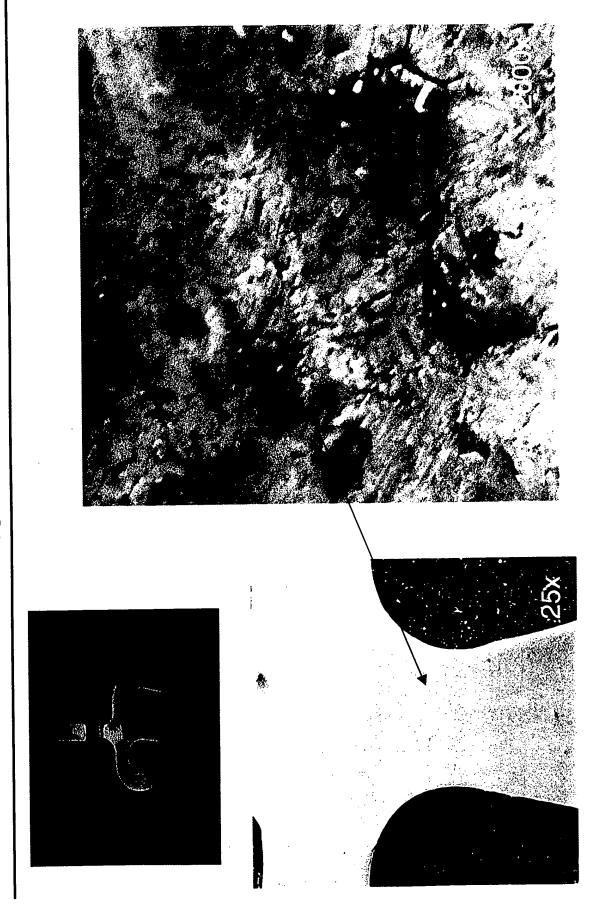


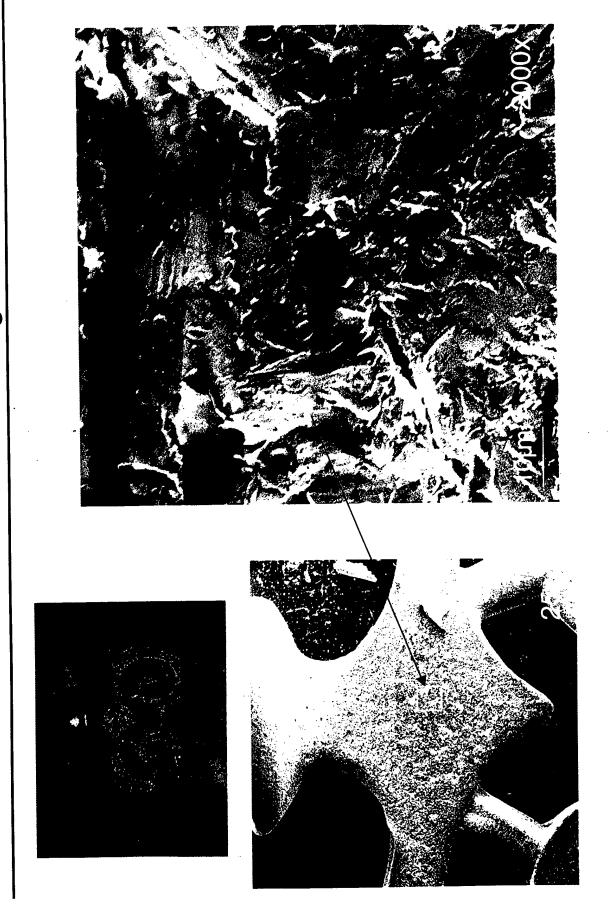


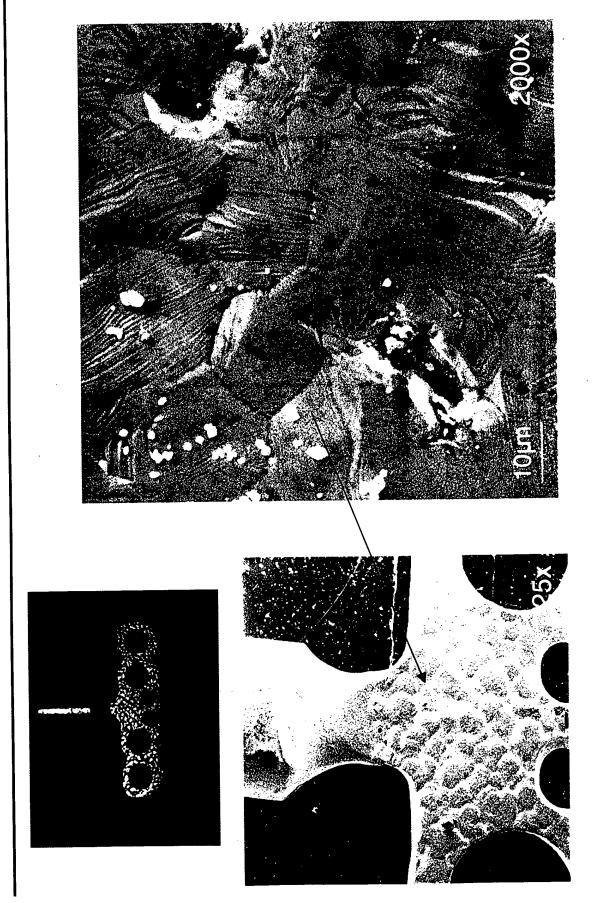


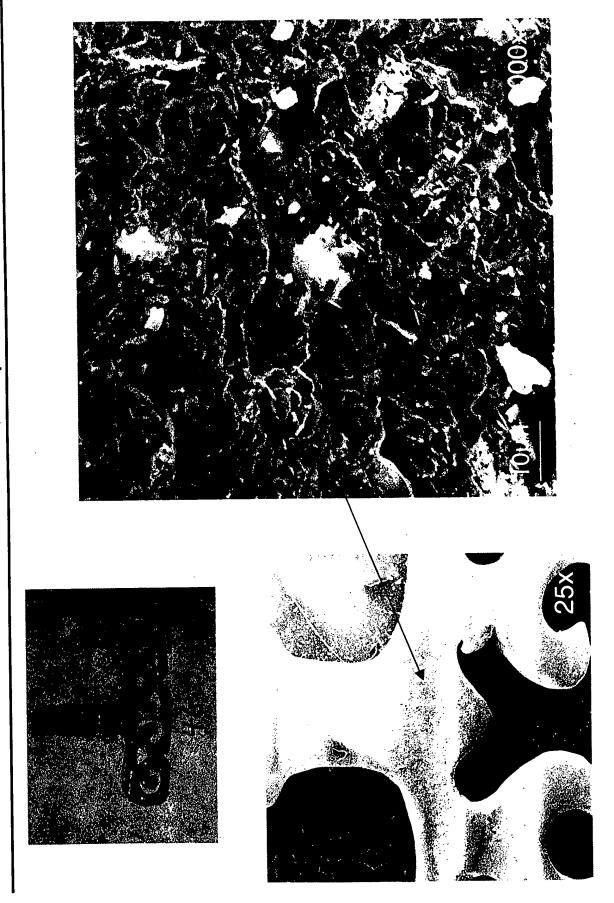




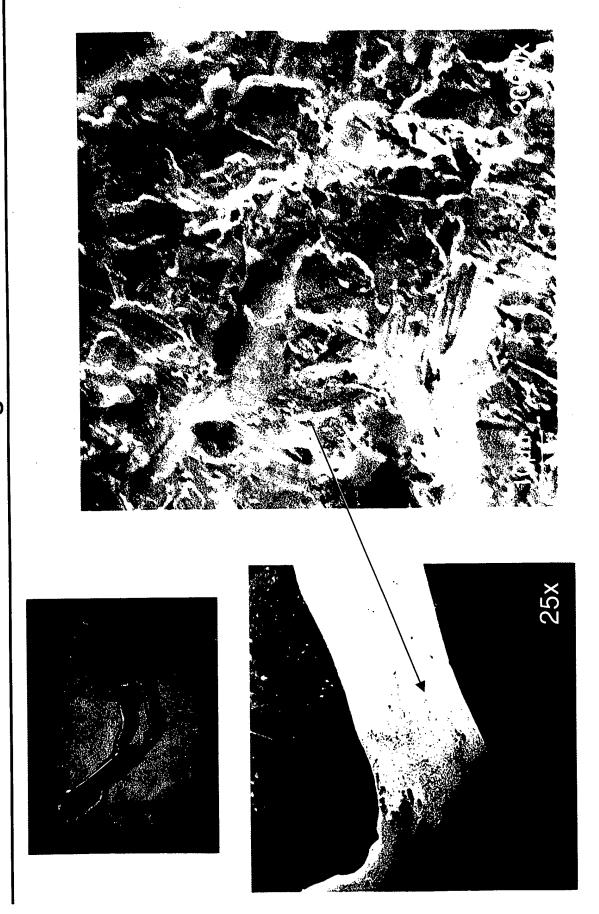


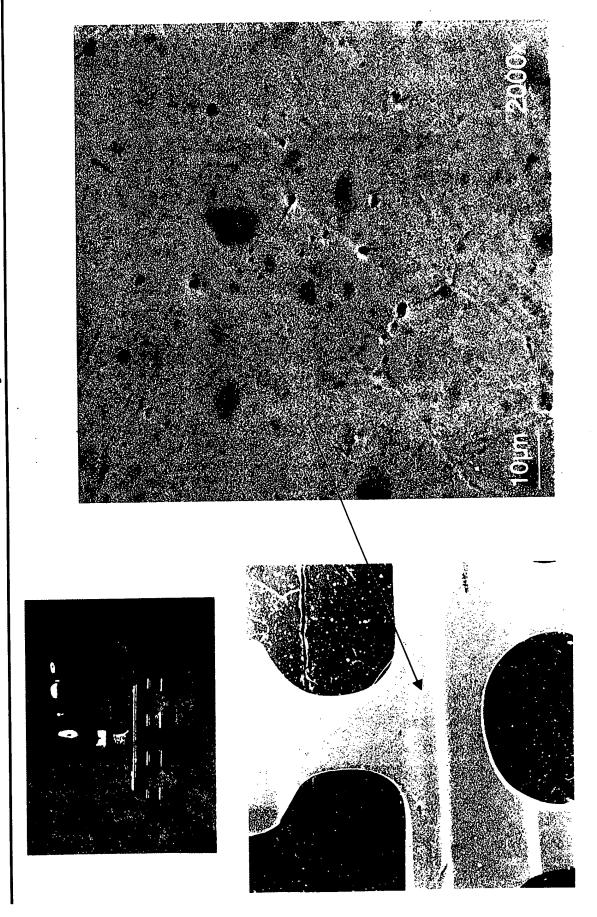


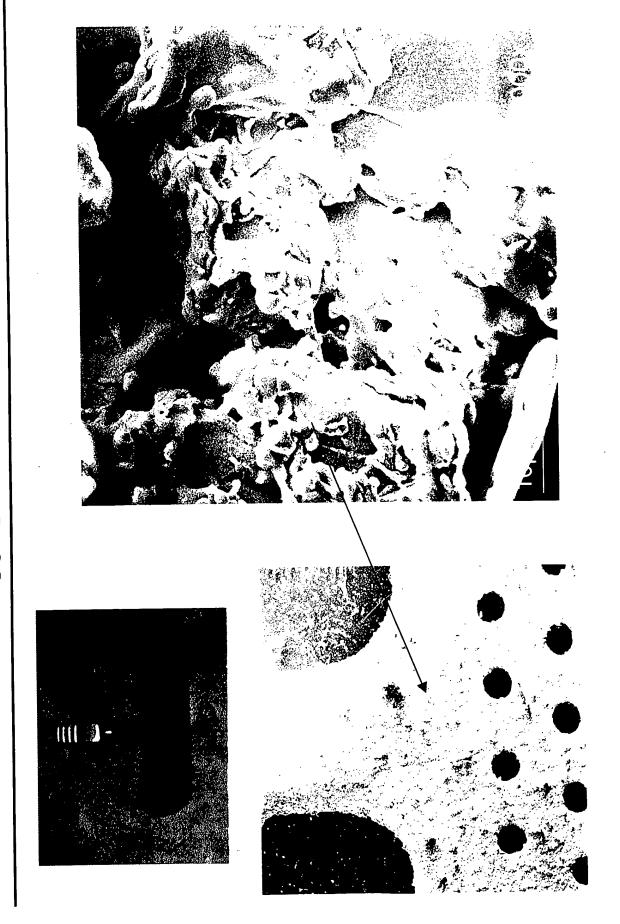


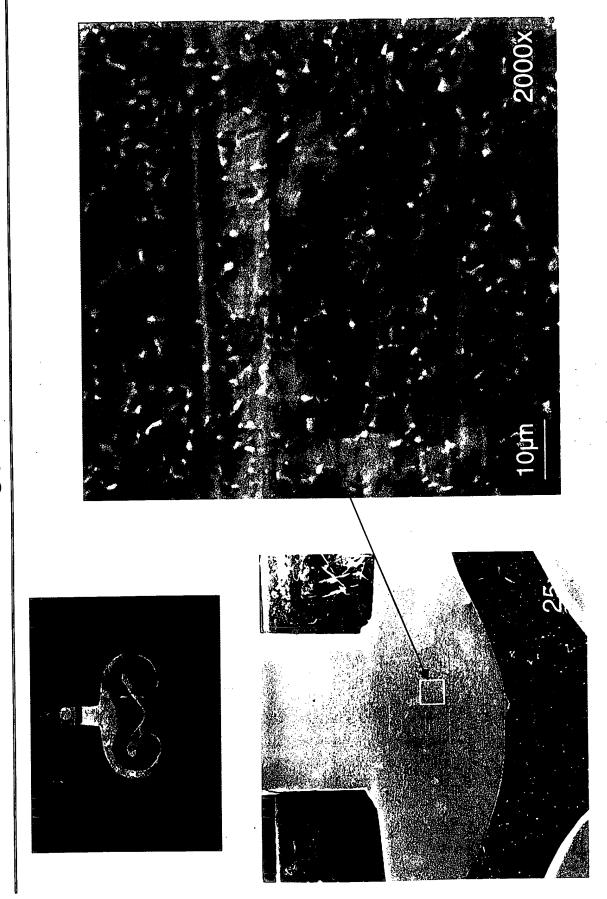


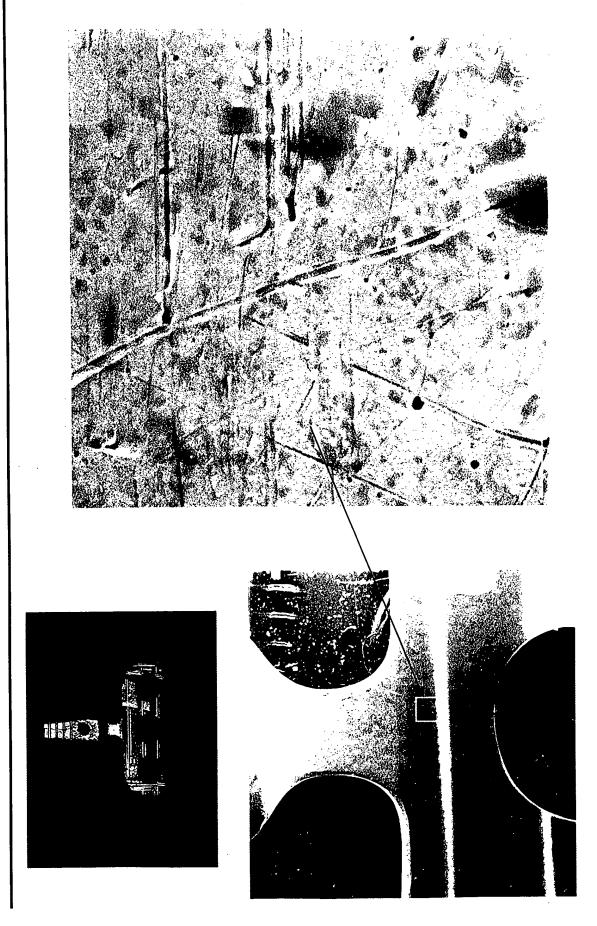


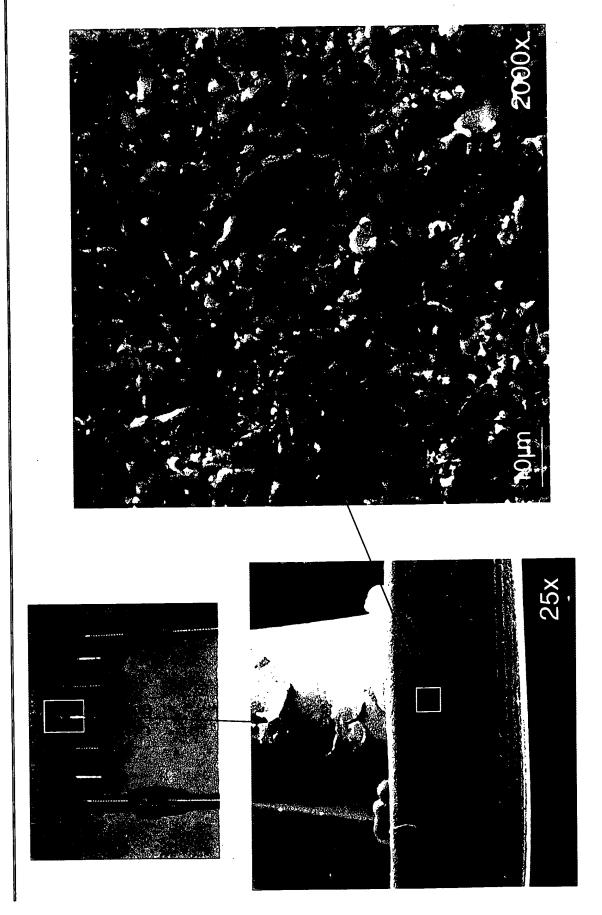


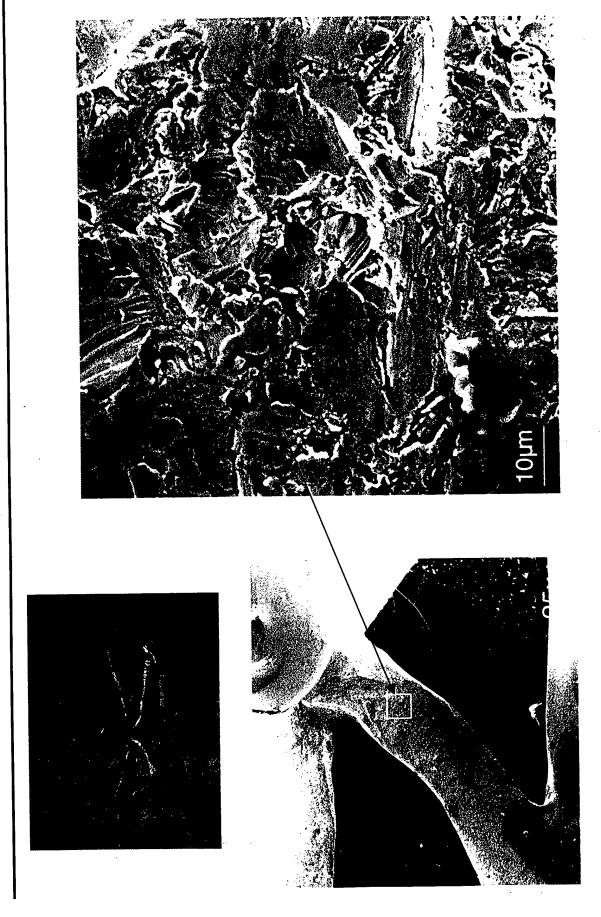


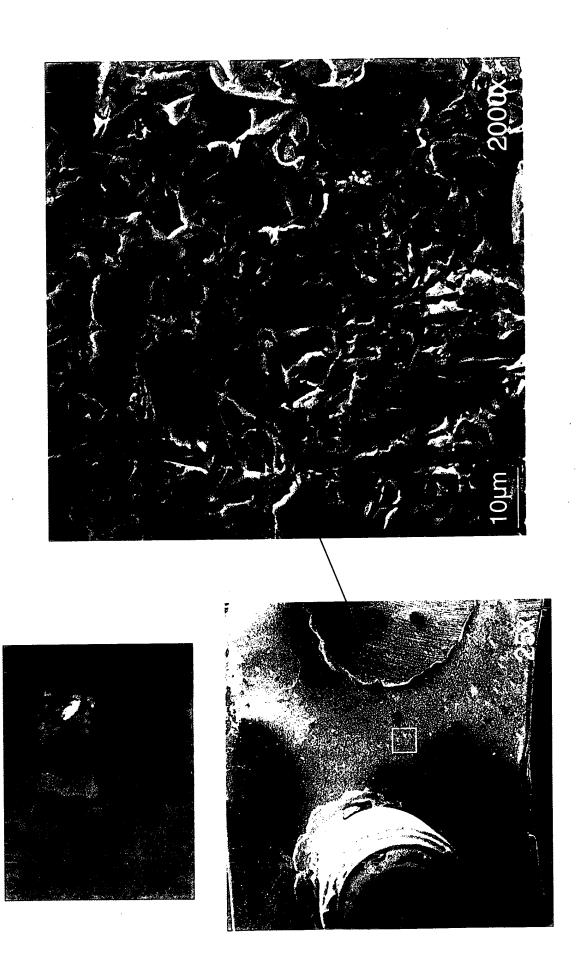


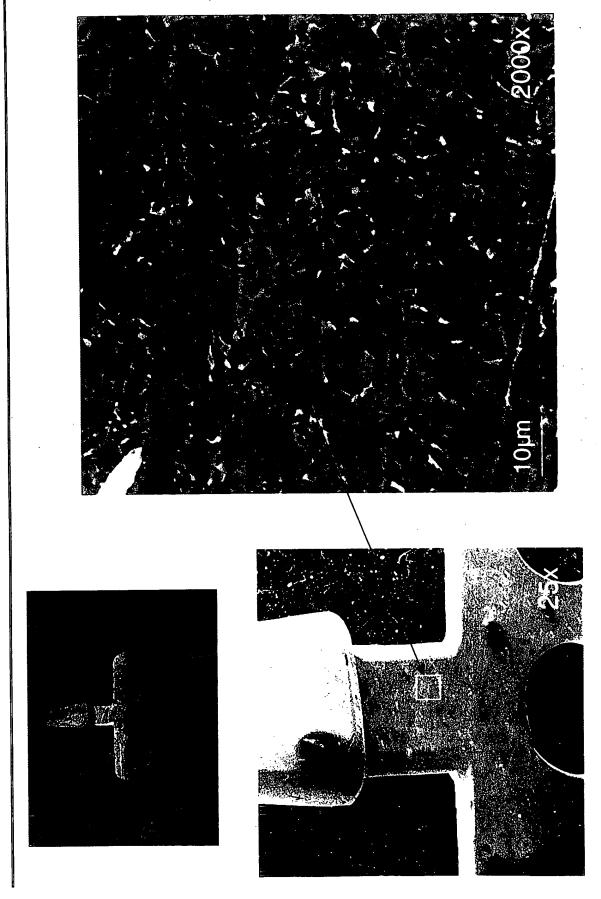


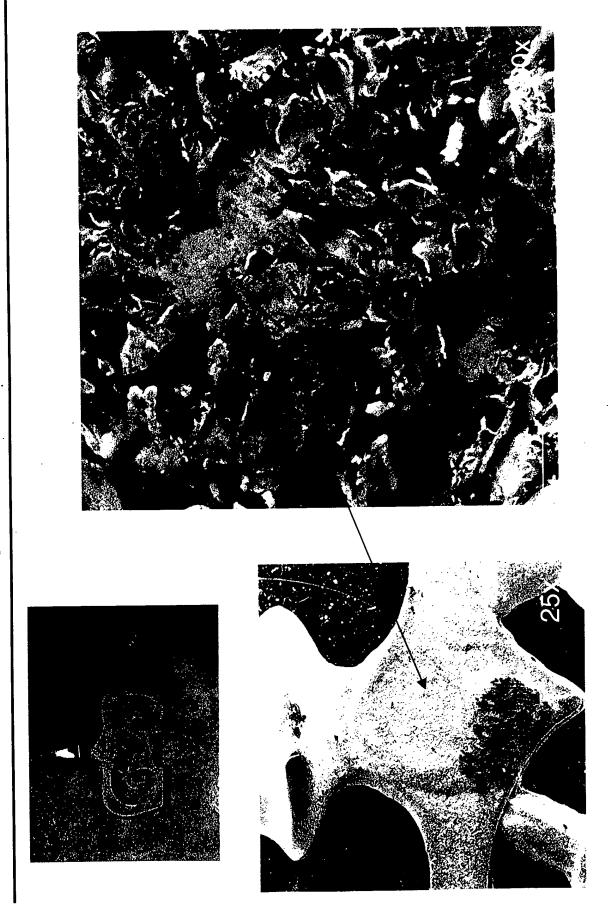


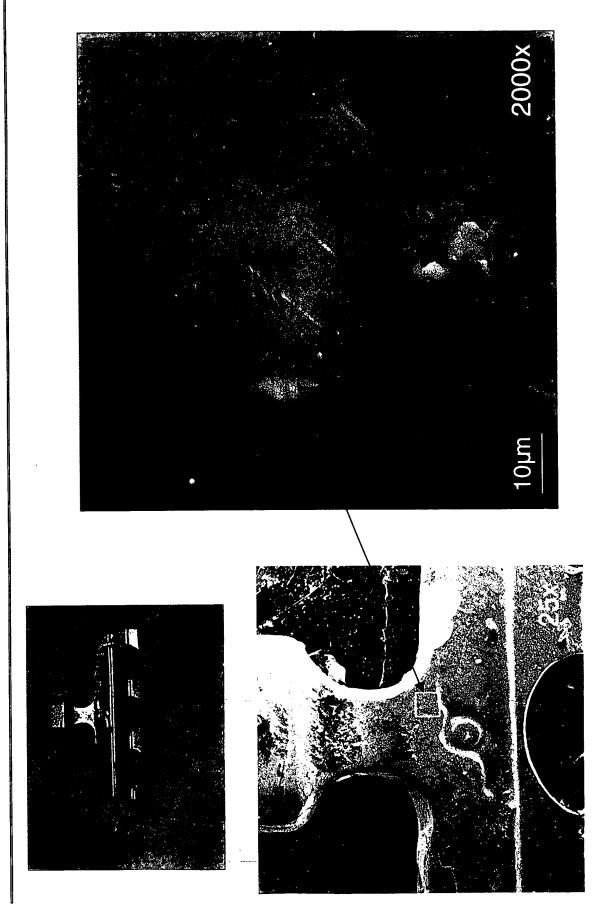


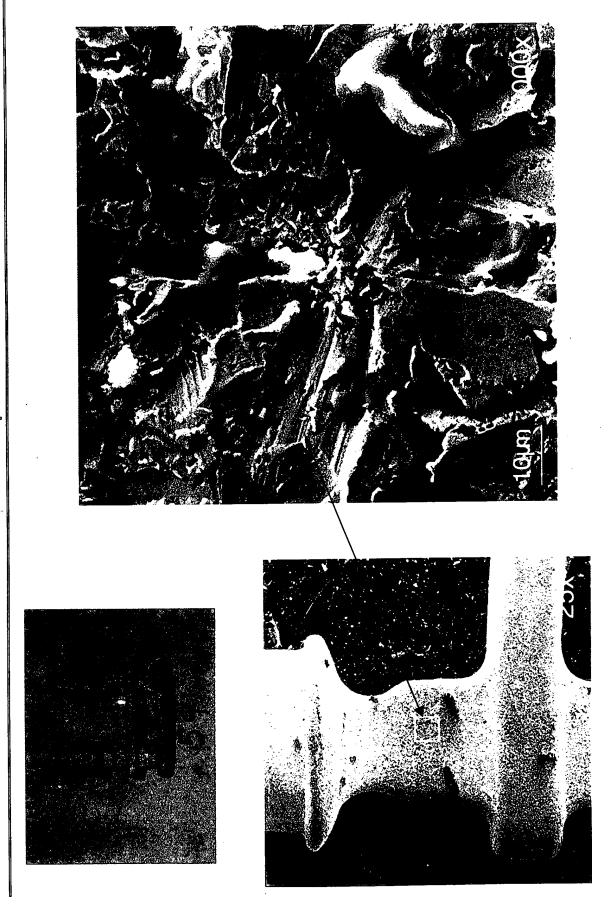


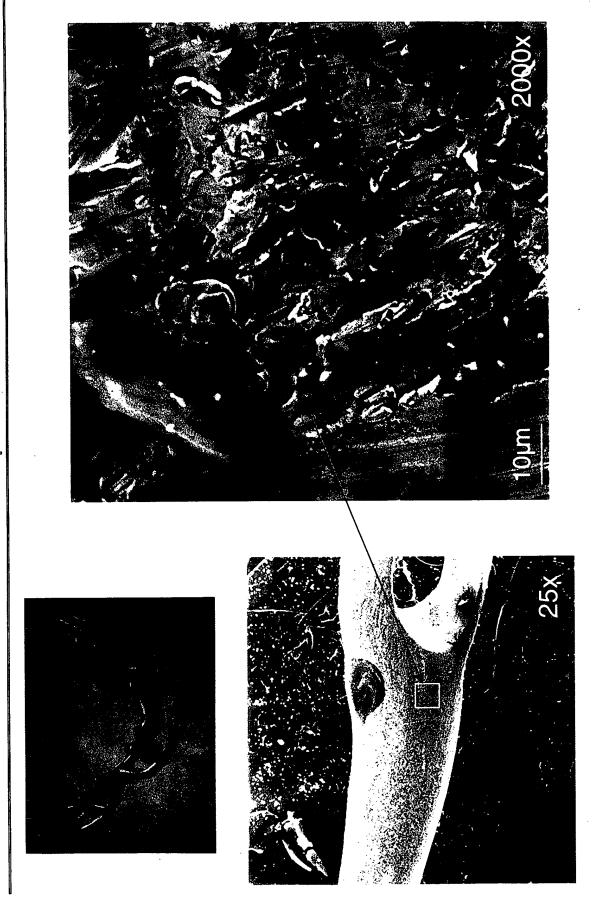


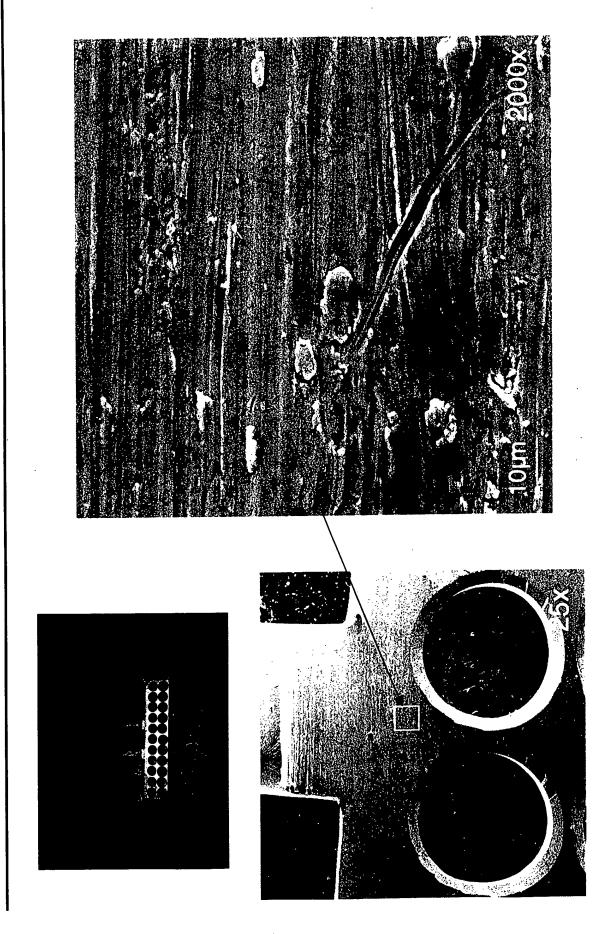












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